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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,490	04/18/2001	Vito V. Florio		7917

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EXAMINER	
TOMASZEWSKI, MICHAEL	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,490	FLORIO ET AL.	
	Examiner	Art Unit	
	Mike Tomaszewski	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *13 August 2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the application filed on 18 April 2001. Claims 1-7 are pending. The IDS statement filed on 13 August 2001 has been entered and considered.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The basis of this rejection is set forth in a two-prong test of:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

(A) For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena that do not apply, involve, use, or advance technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, exemplary claim 7 is drawn to a method comprising the steps of "providing..."; prescription..."; and "evaluation..." It is not clear whether or not the recited steps of "providing..."; prescription..."; and "evaluation..." actively apply, involve, use, or advance the technological arts. In particular, these acts are capable of being performed via pencil and paper. As such, there is no specific requirement with the language of the claim to a practical application WITHIN the technological arts, as there is no requirement for any of the recited steps to be performed electronically or via computerized database components.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, exemplary claim 1 is drawn to a method for control of the indiscriminate use of an unregulated natural substance and/or a derivative of a natural substance in the treatment of an illness or medical condition, and as such, appears to produce a useful, concrete, and tangible result, namely evaluating alternative therapies.

Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claim 7 is deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teagarden et al. (6,356,873; hereinafter Teagarden), in view of Brill (5,299,121; hereinafter Brill), and further in view of Reitberg (US 2002/0032581;hereinafter Reitberg). .

(A) As per Claim 1, Teagarden discloses a management system in a mainstream medical care environment having employee physicians or affiliate medical professionals for delivery of health care services to a patient population wherein a number of said patients are being treated with a limited number of approved traditional therapeutic

medicines in accordance established therapeutic regimens for such approved traditional therapeutic medicines,

wherein the improvement comprises:

(i) Providing a mainstream medical care environment comprising an established health care management system staffed by employee physicians or affiliate medical professionals having responsibility for treatment of a defined patient population, or patient subscribers, with traditional medicines for a given medical condition (Teagarden: col. 6, lines 54-60);

(iii) Means for alerting said employee physicians or affiliate medical professionals responsible for overseeing the care of patients for said given medical condition, of the availability for evaluation, within said established health care management system, of said therapeutic substance as an natural treatment of said given medical illness or condition (Teagarden: col. 11, lines 12-31);

(iv) Means for soliciting said employee physicians or affiliate medical professionals, and their patients suffering from said given medical illness or condition, to participate, within said established health care management system, in said evaluation of said therapeutic substance (Teagarden: col. 11, lines 12-31);

(v) Means for qualifying said patients, within said established health care management system, for participation in said evaluation of said therapeutic substance within said established health care management system (Teagarden: col. 15, lines 46-54; Fig. 14-16); and

(vi) Means for administering said therapeutic substance, within said established health care management system, in accordance with an natural therapeutic treatment regimen, under supervision of said medical professional (Teagarden: pg. 11, col. 32-37).

Teagarden, however, fails to expressly disclose the following:

(vii) Means for monitoring patient response to said therapeutic substance, within said established health care management system, and if efficacious in said natural therapeutic regimen, empowering said patient to specify said therapeutic substance as an natural treatment for his medical illness or condition; and

(ii) Means for identification of an unregulated, therapeutic substance, as a natural for treatment of said given medical condition within said established health care management system.

Nevertheless, these features are old and well known in the art, as evidenced by Reitberg. In particular, Reitberg discloses the following:

(vii) Means for monitoring patient response to said therapeutic substance, within said established health care management system, and if efficacious in said natural therapeutic regimen, empowering said patient to specify said therapeutic substance as an natural treatment for his medical illness or condition (Reitberg: pg. 2, par. [0015], par. [0018]).

One having ordinary skill would have found it obvious at the time of the invention to include the aforementioned feature of Reitberg within the Teagarden system with the motivation of testing therapeutic alternatives for drug treatments (Reitberg: pg. 2, par. [0016].

The collective teachings of Teagarden and Reitberg, however, fail to expressly disclose the following:

(ii) Means for identification of an unregulated, therapeutic substance, as a natural for treatment of said given medical condition within said established health care management system.

Nevertheless, this feature is old and well known in the art, as evidenced by Brill. In particular, Brill discloses the following:

(ii) Means for identification of an unregulated, therapeutic substance, as a natural for treatment of said given medical condition within said established health care management system (Brill: col. 2, lines 19-21).

One having ordinary skill would have found it obvious at the time of the invention to include the aforementioned feature of Brill within the collective teachings of Teagarden and Reitberg with the motivation of selecting an appropriate non-prescription medication (Brill: col. 1, lines 6-8).

(B) As per Claim 2, Reitberg discloses the improved mainstream, health care management system of Claim 1, wherein:

said established health care management system includes means for periodically collecting and cataloging data of patient response to said natural therapeutic regimen over the course of such evaluation (Reitberg: pg. 2, par. [0026]).

(C) As per Claim 3, Teagarden discloses the improved mainstream, health care management system of Claim 2, wherein:

said established health care management system includes means for disseminating, to medical professional and patient, up to date technical and product information related to said given medical condition (Teagarden: pg. 12, lines 12-18; pg. 18, lines 4-9; Fig. 17-18; Appendix D).

(D) As per Claim 4, Teagarden discloses the improved mainstream, health care management system of Claim 1, wherein:

said established health care management system includes means for supply of said natural therapeutic to patients pursuant to a prescription for said natural therapeutic regimen (Teagarden: col. 11, line 34; col. 13, lines 26).

(E) Claim 6 differs from system Claim 1 by excluding technology (i.e., "means for") elements, namely, email or facsimile or telephone. As per these elements, Teagarden teaches:

the use of email, facsimile or telephone to monitor patient therapeutic history (Teagarden: col. 11, lines 15-19).

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the collective teachings of Teagarden, Reitberg and Brill as applied to claim 1 above, and further in view of Miller (Miller, Cyndee. "Major Health Care Marketers Endorse Alternative Treatment" Feb. 3, 1997. Marketing News. Vol. 31, No. 3. pg. 1.; hereinafter Miller).

(A) As per Claim 5, the collective teachings of Teagarden, Reitberg and Brill fail to expressly disclose the improved mainstream, health care management system of Claim 1, wherein:

said mainstream, health care management system provides for patient reimbursement or insurance coverage for said natural therapeutic dispensed pursuant to a prescription written by said medical professional.

Nevertheless, this feature is old and well known in the art, as evidenced by Miller. In particular, Miller discloses the following:

said mainstream, health care management system provides for patient reimbursement or insurance coverage for said natural therapeutic dispensed pursuant to a prescription written by said medical professional (Miller).

One having ordinary skill would have found it obvious at the time of the invention to include the aforementioned feature of Miller within the collective teachings of Teagarden, Reitberg and Brill with the motivation of capitalizing on trends showing alternative medicine's trend growing mainstream acceptance (Miller).

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Teagarden in view of Reitberg.

(A) As per Claim 7, Teagarden discloses the method for control of the indiscriminate use of an unregulated natural substance and/or a derivative of a natural substance in the treatment of an illness or medical condition, the improvement comprising:

(ii) Prescription of said substance within said environment by a medical professional for treatment of said patient in accordance with a treatment regimen specific for said patient (Teagarden: col. 7, lines 35-38).

Teagarden, however, fails to expressly disclose the following:

(i) Providing a mainstream medical environment for evaluation of safety and efficacy of unregulated natural substance and/or a derivative of a natural substance, wherein a patient suffering from an illness or medical condition is initially evaluated within said environment to determine said substance's potential suitability for treatment of said patient (Reitberg: pg. 2, par. [0022]; pg. 3, par. [0029]); and

(iii) Periodic evaluation of said patient response to said substance by said medical professional (Reitberg: pg. 2, par. [0022]).

Nevertheless, these features are old and well known in the art, as evidenced by Reitberg. In particular, Reitberg discloses the following:

(i) Providing a mainstream medical environment for evaluation of safety and efficacy of unregulated natural substance and/or a derivative of a natural substance, wherein a patient suffering from an illness or medical condition is initially evaluated within said environment to determine said substance's

potential suitability for treatment of said patient (Reitberg: pg. 2, par. [0022]; pg. 3, par. [0029]); and

(iii) Periodic evaluation of said patient response to said substance by said medical professional (Reitberg: pg. 2, par. [0022]).

One having ordinary skill would have found it obvious at the time of the invention to include the aforementioned feature of Reitberg within the Teagarden system with the motivation of testing therapeutic alternatives for drug treatments (Reitberg: pg. 2, par. [0016].

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches a computer system and method for suggesting treatments for physical trauma (4,839,822); an all care health management system (5,301,105); a prescription management system (4,839,822); and a computer system for decision support in the selection of diagnostic and therapeutic tests and interventions for patients (6,029,138).

The cited but not applied prior art also includes non-patent literature articles by Bette Popovich ("Paying the Bill for Alternative Medicines" Nov. 8, 1999. Chemical

Market Reporter. Vol. 256, Iss. 19. pg. F8.) and Steve Woodward ("Old Remedies for the New Age" Oct. 23, 1996. The Oregonian. pg. B1.).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MT 8.15.05

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER